

Check out the SPL Working Group WIKI @:
<http://spl-work-group.wikispaces.com>

Questions on SPL:

ER/DL regulatory questions? Send to edrls@fda.hhs.gov
SPL technical questions? Send to spl@fda.hhs.gov

Meeting Minutes:

Proper usage of the Proprietary Name Suffix Data Element in Listing SPL Documents

- While proper names may include dosage forms, routes of administration, etc. FDA does not accept Proprietary Name data with these suffixes.
- Do not include qualifiers in the Proprietary Name (dosage forms, routes of administration, USP) or in the Generic Name
- Acceptable qualifiers include Extended Release, Controlled Release, ER, CR, XR, SR, etc.
- Currently, the suffix does not appear on the rendition displaying on DailyMed

Down stream users – how does DailyMed relate to NDC Directory? DRLS pulls information from SPL files in eList, not from DailyMed. This allows the unapproved or other products not posted on DailyMed NDC information to be added to NDC Directory.

NDC (Paper version) – We delisted in paper form; however, the codes are still in the NDC Directory. What should we do? Contact DRLS.

Provision of Images (quality, size, amount)

- Supply one image [representative sample] for each strength, of either carton or label.
- Recommended that the image contain as much info as possible. Example: For a tube of toothpaste (with minimal information on the tube) packed in a box (that contains Drug Facts on the panel), the carton has more information (and could be more useful to a reviewer)

What is the rationale for providing the representative sample? It's the law.

How does the DRLS group extract the information from the representative sample for the NDC Directory? They use the SPL metadata directly. They do not extract the data

from the image.

New validation Procedure Alerts

- Image size
Keep the file size below 1 MB
- Images in Principal Display Panel Sections
Each image should have its own major section
- How quickly are these validation alerts implemented w/in eList? As quickly as possible

Common SPL errors discussion

- SPL created with XForms: if you put the ingredient information after the packaging information, you are likely to get an error. Make sure that you use XForms 1.02
- XForms does not currently allow saving of UNII code information containing symbols – Global Submit has been notified
- SPL files not received in folders
- Principal Display Panel – this should be put in a major section
- Medication Guide should be placed in a major section, with appropriate LOINC code. Do not place it in a subsection.
- Don't send in Excel documents, or print-screens of Xforms
- When you submit Labeler Code, a DUNS number is included. If you get a message about a mismatch on the NDC, check that your DUNS number matches that used in the Labeler Code.
- Some companies send eCTD through the OC gateway – don't do that!
- When you're adding the file extension to your files, use lower-case (.xml, .jpg)
- *Product with tabs and caps in one label. One additional manufacturer overseas that only produces tabs. How do we list? Put both in the Establishment Registration; only one Drug Listing is needed.*
- *Have a product with bottles of 50 and 100. Company wants to discontinue the bottle of 100 and start producing bottle of 30. How do we list? Remove the 100 count, add in the 30 count.*
- *Do we need to list bulk product packaging? If you're marketing it, then you should list it*
- *How do we include monograph information? Part + number.*

Delayed to November 18):

- Review of Draft guidance SPL technical Q&As

FYIs:

- Additional way to find UNIIIs: New Inactive Ingredient search at FDA:
<http://www.accessdata.fda.gov/scripts/cder/iig/index.cfm>
- Several new eBooks (all at <http://spl-work-group.wikispaces.com/SPL+eBooks+-+Graphic+Guides>)
 - Locating Gateway coreIDs and downloading SPLr4 error messages
 - Using SPLr4 Xforms to Save or Reopen SPL Documents
 - Creating Listing SPL Documents for Products Which are Both Cosmetics and Drugs
 - Creating Homeopathic Drug Listing SPL Documents
 - Creating Cosmetic Drug Listing SPL Documents
 - Creating Bulk Ingredient Listing SPL Documents

Currently there are 5396 SPL on [DailyMed](#)

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